



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 20 2001

Patrick L. Clary, M.D.
Seacoast Hospice
10 Hampton Road
Exeter, New Hampshire 03833


Dear Dr. Clary:

Thank you for your letter addressed to Senator Bob Smith regarding opioid analgesics as a pain treatment for people with chronic pain. Senator Smith has asked us to respond directly to you.

Currently, the Food and Drug Administration (the Agency) has an open docket to receive comments on opioid analgesics. We are forwarding your letter to docket number 01N-0256 where it will be considered by the Agency.

Thanks again for contacting Senator Smith concerning this matter.

Sincerely,


Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: Dockets Management Branch
01N-0256

The Honorable Bob Smith
United States Senate
Washington, D.C. 20510-2903

01N-0256

C192 /ANS

BOB SMITH
NEW HAMPSHIRE

RANKING MEMBER
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United States Senate
WASHINGTON, DC 20510-2903

ARMED SERVICES

July 27, 2001

Melinda K. Plaisier
Associate Commissioner for Legislative Affairs
Food and Drug Administration
U.S. Department of Health and Human Services
Parklawn Building
5600 Fishers Lane, Room 15-55
Rockville, Maryland 20857

Dear Melinda:

I have recently been contacted by Dr. Patrick Clary of Exeter, New Hampshire, concerning opioid analgesics as a pain treatment for people with chronic pain. Dr. Clary stipulates that opioid analgesics will significantly reduce the amount of pain that his and other patients incur.

Any information you can provide Dr. Clary and myself regarding opioid analgesics and the recent hearing that was conducted on opioid analgesics would be graciously appreciated. Please respond directly to him in Exeter and please carbon copy me with your response.

Thank you in advance for your assistance.

Sincerely yours,



Bob Smith, U.S.S.

/aap
Enclosures

01N-0256

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Senator Bob Smith
1750 Elm Street
Suite 101
Manchester, NH 03104

Dear Senator Smith:

According to the *Federal Register* "notice of hearing" May 3, 2001, the Anesthetic and Life Support Drugs Advisory Committee intends to discuss the medical use of opiate analgesics at hearings June 14th and 15th. The published agenda suggests that the area of concern is the "risk to benefit ratio" of the extension of opiate treatment into the area of chronic nonmalignant pain, particularly with reference to abuse potential, diversion and addiction issues.

As a long-time hospice and primary care physician who serves many of your constituents I am writing to express my informed sense of alarm and to ask for your support with this issue.

I am a physician graduate of Georgetown University School of Medicine and have served in various positions within three different hospices since 1988. I am licensed in New Hampshire, Board Certified in Family Practice, and in Hospice and Palliative Care, and currently work as the half-time Medical Director of Seacoast Hospice, the only nonprofit freestanding hospice in New Hampshire. In addition to hospice work, caring for people at the end of their lives, I continue to own and direct a family practice providing primary medical care to 25,000 citizens of New Hampshire and Maine. I also work as the medical director of the largest Nursing Home in my home county. I have been practicing medicine for 21 years.

Before attending college and medical school I served in the US Army, trained as a medical corpsman, and spent the year of June 13th, 1969 through June 12th, 1970 as an infantry medic in Vietnam. I was decorated modestly and honorably discharged with the rank of Specialist 5th Class.

I began hospice work in 1988 because it was necessary rather than because of any intrinsic interest the work held for me. Our patients were dying in pain and it was clear that was absolutely wrong. The therapeutic solution was not rocket science but the straightforward use of one of the oldest groups of medications used in Western medicine: opioid analgesics. Yet over and over again I have seen the same barrier to effective pain treatment at the end of life. This barrier is fear. Doctors still tell me they are afraid of the Drug Enforcement Agency, and they tell me they are afraid their patients are going to "get addicted."

As a result, half of all patients dying in good tertiary care hospitals continue to die in pain, and as many as 80% of nursing home patients die in pain. This is so clearly wrong that I don't wish to belabor it. I am certain that it is not the Food and Drug Administration's intention in formulating and enforcing regulations to increase the proportion of people dying in pain. That however has been the overall effect of oversight in the past, and threatens to continue to be true in the future. Please influence the FDA to consider such unwanted consequences as the agency moves toward further rulemaking in this area.

News media reports suggest that the FDA is considering limiting the privilege of opioid prescription to specialists in pain management, and that chronic nonmalignant pain patients may be excluded from access to opioid therapies. My observations of this group of specialists suggest that they prefer to avoid the use of opioids for chronic pain in general.

Conversations with pain management doctors reveal that fear is a barrier in this area even for the highly trained. Economic considerations also drive treatment in the direction of performing expensive and repetitive procedures for pain relief even when noninvasive use of opioid analgesics would likely be more cost-effective. One of my colleagues in pain management once confessed to me that he knew that opioids would take care of most pain issues, "But they come expecting eight hundred dollar procedures so who am I to substitute an eighty-dollar office visit for that?"

Those of us in hospice medicine were the first to make the observation that "getting ahead of the pain" with an opioid often restored function in malignant pain. Time-release versions of these medications have allowed effective treatment without the need for dosing every three to four hours, helping in both the logistics and psychology of adherence to any pain regimen. When any pain is effectively treated with a dose of time-release opioids we often find that the dose stabilizes for months or years at a time, only requiring a change in dosage when the disease changes.

In hospice medicine we really don't depend on the distinction between chronic malignant and nonmalignant pain. It isn't always even possible to make that distinction. It is always possible to make the distinction between mild, moderate, and severe pain. We begin treatment on the World Health Organization "pain ladder" with weaker medications such as acetaminophen and non-steroidal anti-inflammatories, tending toward stronger opioids for more severe pain.

We do tend to use opioids more liberally in our patients who are dying.

Pain in the context of approaching death is a more hopeless experience, therefore more difficult to control without opioids, and may well get in the way of completing emotional and spiritual work that will ease the burden not only for the dying but for their survivors.

I am not, however, proposing that the FDA ought to establish dying as a prerequisite for opioid use. Prognosis is a very difficult undertaking little taught in medical school with limited research support. It's very difficult to say when a patient suffering from a chronic disease is actually dying. It is so difficult, in fact, that prognosis appears to be the most impermeable barrier to hospice care. Half of the patients in my hospice are admitted less than 15 days before death, and we only care for 20% of all of the dying even in that context. These statistics are true nationally. Limiting use of opioids will lead to unrelieved suffering among the dying even if the FDA

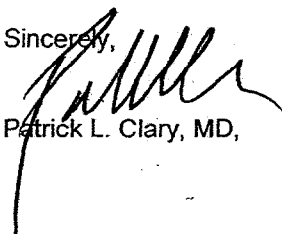
defines hospice patients as appropriate for treatment with these agents. A vast majority of the dying never come to hospice care.

While my knowledge of the legitimate use of opioid analgesics comes primarily from 13 years of the study and practice of end-of-life care, I am also concerned with my primary care patients in the middle of their lives. It's our practice policy to refer patients with nonmalignant chronic pain syndromes to pain management specialists to establish treatment plans, but I often find myself comfortable following them on opioid analgesics after therapy has been established. Even in my well-served area there aren't enough pain management specialists to follow all chronic pain patients adequately. One of my patients with a diabetic neuropathy told me that he felt that he had gotten his life back after effective pain management was established with small around-the-clock doses of methadone, a shift in treatment I initiated after failure in specialty care. The effective treatment of chronic pain in the middle of people's lives is often very gratifying, though perhaps not as essential as end-of-life care.

I understand the policy concerns of those who seek to limit the diversion of opioids and the epidemic of addiction. However, when they look at what's at stake here, they must consider that rules increasing the barriers to effective pain management will condemn citizens to living and dying in pain. I can't help thinking of a scene near the end of the recent movie "Traffic," in which the "war on drugs" is defined as a war on our own people. If the FDA raises barriers to effective pain management, whatever their motives, they will be making war on the most helpless of our citizens, the dying and those in chronic pain. Two and half million Americans die every year, many more than half of them in pain, and many millions more live in chronic pain. I can tell you that the situation now is more horrible than anything I ever saw in Vietnam. Please don't let the FDA take actions to make it worse.

Thank you for your consideration and support.

Sincerely,



Patrick L. Clary, MD,